

Remarks

By the foregoing Amendment claims 1-3, 8, 9, 11 and 20 are amended, claim 7 is cancelled and new claims 21 and 22 are added. Applicant respectfully submits that no new matter has been added by this Amendment and that no additional searching is required as all the limitations of the claims have been present in the originally filed claims. Entry and favorable consideration thereof is earnestly requested.

The Examiner has rejected claims 1-11, 14 and 20 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,941,882 ("the '882 patent"). These rejections are respectfully traversed.

Initially applicant notes that the '882 patent is not an interference screw according to the present invention. An interference screw is inserted into an opening side by side with a tendon, the interference screw exerting lateral force on the tendon to maintain the tendon in the hole. (See Figs. 8 and 9 of the present application) The '882 patent on the other hand is a suture anchor where only the anchor screw is inserted in the opening with suture loop feeding through channels in the anchor screw, the suture loop then being attached to the tendon. ('882 patent, FIG. 4, 7A & 7B).

A. 35 U.S.C. §103(a) rejections

Claim 1 requires among other elements "a screw having a screw body made of a biodegradable material and configured as an interference screw for anchoring a transplant in an opening in a bone" and "a tool having up to five drive elements for inserting into said up to five grooves, and having a projection corresponding to said recess in said facial end face of said head portion of said screw, said projection can be introduced into said recess for centering said tool on said screw."

Claim 20 requires among other elements "an interference screw made of a biodegradable material for anchoring a transplant in an opening in a bone" and "at least

one axially extending groove cut into and extending along an outer side of said head and an entire length of said shaft, said at least one groove being provided for inserting a drive element of a driving tool therein."

1. Patentability of Both Claims 1 and 20

The Examiner has submitted that it would have been obvious to modify the anchor screw taught in the '882 patent to be bio-absorbable and that bio-absorbable interference screws for fixing ligaments is known in the art. (12/17/03 Office Action, p. 2, sec. 1). Applicant respectfully disagrees that it would be obvious to modify the anchor screw taught in the '882 patent to be bio-absorbable, rather, the '882 patent teaches away from this suggested modification. If the anchor screw taught in the '882 patent was bio-absorbable, the suture arrangement would completely fail causing the tendon to pull loose from the bone. The anchor screw in the '882 patent must never degrade because the ligament never attaches directly to the bone. Rather, the ligament is only attached to the suture which in turn is only connected to the anchor screw. ('882 patent, col. 4, lines 4-8, 18-9, 43-56, FIGS 7A & 7B). Applicant therefore respectfully submits that because modifying of the anchor screw of the '882 patent to comprise a bio-absorbable material would result in complete failure of the device, such modification cannot be obvious.

Applicant therefore submits that any modification of the anchor screw of the '882 patent to comprise a biodegradable material as required by claims 1 and 20 requires converting the anchor screw to an interference screw. This however, is a complicated modification. The modification would include initially at the very least, 1) eliminating the suture attachment arrangement; 2) providing finer outer threads so as not to damage the ligament inserted into the hole next to the screw; 3) tapering the body of the screw as the screw threads directly engage with the transplant and it is very important that the transplant not become damaged; and 4) using a different drilling tool to provide a hole configuration (i.e. smaller in diameter and tapered) that is appropriate for an interfer-

ence screw. Applicant respectfully submits that there is no motivation to embark on this type of extensive redesign of the '882 patent anchor screw as suggested would be obvious.

Applicant further submits that it would not be obvious to further modify the anchor screw taught in the '882 patent to comprise an interference screw that has axially extending grooves. While in the '882 patent teaches an anchor screw having axially extending grooves to receive a tool (FIGS. 6 & 8) it would not be obvious use these axially extending grooves with the modified interference screw. As previously stated, unlike an anchor screw, the tendon is directly inserted into the hole side by side with the interference screw such that lateral pressure from the interference screw holds the tendon in place in the hole. The shear depth and size of the grooves 118 (FIG. 6) of the anchor screw taught in the '882 patent are not usable in an interference screw arrangement. For instance, once the tool 110 with protrusions 150 (FIG. 8) is removed from the anchor screw, two large axially elongated grooves 118 are left in the sides of the anchor screw. The ligament or tendon will penetrate these large deep grooves such that the clamping force exerted by the anchor screw is uneven and severely reduced, which is highly undesirable. Therefore, applicant respectfully submits that these large deep grooves would have to be modified if the anchor screw is to be modified to be an interference screw, which would be required if it were to be made of a biodegradable material.

In view of the forgoing, applicant respectfully submits that because the '882 patent fails to teach or suggest a screw having a screw body made of a biodegradable material and configured as an interference screw for anchoring a transplant in an opening in a bone as required by claims 1 and 20, it cannot render either claim obvious.

2. Patentability of Claim 1

Further, claim 1 is patentable because it provides for axially extending grooves for driving the screw having a recess for centering the driving tool about the screw. The '882 patent on the other hand fails to teach or suggest a tool having up to five drive elements for inserting into the up to five grooves, and having a projection corresponding to a recess in the facial end face of the head portion of the screw as further required by claim 1.

As previously discussed, the screw taught in the '882 patent must be substantially redesigned to be biodegradable so as to be used as an interference screw. Assuming the screw is so redesigned, the axially extending grooves taught by the '882 patent must also be modified so as to be usable with an interference screw.

For instance, the '882 patent teaches use of two driving elements 150 (FIG. 8) to engage with axially extending grooves 118 (FIG. 6), which would yet still have to be modified as previously discussed, nowhere however does the '882 patent teach or suggest a tool having ... a projection corresponding to a recess in the end face as required by claim 1. Rather, when looking at FIGS 6 and 8 it can be seen that this feature is unnecessary because of the large size of the two driving elements and because of the depth of the grooves. In contrast, the multiple driving elements of the present invention are much smaller having a lower profile with rounded axially extending grooves such that the projection facilitates centering of the tool for the application of enough force to drive the interference screw into the hole. This is a problem that was not faced by the '882 patent because it is an anchor screw. The structure of the anchor screw as taught in the '882 patent however, is not universally applicable to an interference screw. As previously discussed, the deep grooves taught in the '882 patent are highly disadvantageous to use with an interference screw because a ligament or tendon will penetrate these large deep grooves such that the clamping force exerted by the screw is uneven and severely reduced. Any failure or an increased risk of failure is unacceptable, be-

cause if the tendon or ligament breaks loose, additional surgery is required to repair the failure, which may or may not be possible.

Therefore, even if the '882 patent were substantially modified to comprise an interference screw, the axially extending grooves would have to be redesigned to function properly as an interference screw. In addition, even if the screw and the grooves were so modified, the screw still lacks a recess in the screw head for receiving a projection on the tool for centering the tool as required by claim 1.

In view of the forgoing, applicant respectfully submits that because the '882 patent fails to teach or suggest a screw having a screw body made of a biodegradable material and configured as an interference screw for anchoring a transplant in an opening in a bone and a tool having up to five drive elements for inserting into said up to five grooves, and having a projection corresponding to said recess in said facial end face of said head portion of said screw, said projection can be introduced into said recess for centering said tool on said screw as required by claim 1, it cannot render it obvious.

B. U.S. Patent No. 6,629,977 to Wolf

The Examiner has noted U.S. Patent No. 6,629,977 to Wolf ("the '977 patent") and submitted that bioabsorbable interface screws for fixing ligaments is known in the prior art, citing the '977 patent. (12/17/03 Office Action, p. 2, sec. 1). The '977 patent teaches an interference screw according to the prior art having a center hex receptacle for receiving a driving tool ('977 patent col. 1, lines 60-3, FIG. 2) as discussed in the specification of the present application at p. 2, lines 20-28 and p. 3, lines 1-14. According to the object of the invention, this type of interference screw can not handle high driving forces especially for smaller and thinner screw constructions. (p. 3, lines 15-8).

The '977 patent however fails to teach or suggest either: up to five axially extending grooves cut into an outer side of said screw body, said up to five grooves extending along said head portion and an entire length of said shaft portion, and at least one re-

cess is provided in said facial end face of said head portion as required by claim 1; or at least one axially extending groove cut into and extending along an outer side of the head and an entire length of the shaft, the at least one groove being provided for inserting a drive element of a driving tool therein as required by claim 20.

The '977 patent addresses this problem with a different structure. For instance, the '977 patent teaches that the screw includes "a head provided with a specially designed Delta drive socket for receiving a Delta drive screwdriver or a traditional hex-head screwdriver" and that the "unique drive socket of the interface screw of the present invention optimizes the torque capacity of the screw." (col. 1, lines 61-5). The '977 patent further teaches that to "maintain , [sic] wall thickness, the drive socket is tapered in correspondence with the tapered outer profile of the device." (col. 1, lines 65-7). Therefore, the '977 patent specifically identifies the problem associated with application of a high torque to the screw and addressed this problem by maintaining the wall thickness with the tapering. (See also col. 3, lines 6-10 "The Delta drive socket 35 permits increased torque capacity while minimizing the problem of stripping the drive portion of the screw 10."). So then, the '977 patent teaches away from the use of axially extending grooves because it teaches a different methodology to solve the same problem.

The present application however, solves this problem in a completely different manner, namely by axially extending grooves on the outside of the interference screw. Applicant respectfully submits, that there is no motivation to modify the '977 patent in view of the '882 patent because the '977 patent had already addressed the problem of applying a large amount of torque to the screw with a different screw structure. Even if the '977 patent were modified to include axially extending grooves according to the '882 patent, this modified screw would have to be further modified because the axially extending groove arrangement taught in the '882 patent would not work with an interference screw. Rather, the axially extending grooves would have to: be reduced in size and depth; the shape of the grooves would have to be changed to eliminate the sharp edges which would cut and/or damage the tendon or ligament; and additional grooves

would have to added along the length of the screw because the small size of the tool protrusions for interacting with the grooves would not provide the strength necessary for the applied torque to insert the screw. Still further, a projection should then be added to the tool to interface with a recess on the screw head to center the driving tool. This constitutes a complete redesign of the screw taught in the '977 patent to eliminate a problem that was already identified and addressed by a different structural configuration. Applicant therefore submits that there is no motivation to disregard one of the primary teachings of the '977 patent to solve a problem already addressed by the '977 patent screw structure.


In addition, as presented in connection with claims 1 and 20 above, even if the '977 patent was modified in view of the '882 patent, the axially extending grooves taught in the '882 patent would have to be redesigned to function properly with the interference screw taught in the '977 patent. Still further, even if the interference screw taught in the '977 patent and the grooves taught in the '882 patent were so modified, this redesigned screw still lacks a recess in the screw head for receiving a projection on the tool for centering the tool as required by claim 1.

Applicant therefore submits that because the '977 patent fails to teach up to five axially extending grooves cut into an outer side of said screw body, said up to five grooves extending along said head portion and an entire length of said shaft portion, and at least one recess is provided in said facial end face of said head portion as required by claim 1, it cannot render claim 1 obvious. Applicant further submits that because the '977 patent fails to teach at least one axially extending groove cut into and extending along an outer side of the head and an entire length of the shaft, the at least one groove being provided for inserting a drive element of a driving tool therein as required by claim 20, it cannot render claim 20 obvious. Applicant still further submits that there is no motivation to disregard the teachings of the '977 patent in view of the '882 patent as the '977 patent already teaches a solution to the problem and that therefore any combination of these references cannot be obvious.

Page 13
Serial No. 09/745,960
Response to Official Action

It is respectfully submitted that claims 1-11, 14 and 20-22, all of the claims remaining in the application, are in order for allowance, and early notice to that effect is respectfully requested.

Respectfully submitted,



Wesley W. Whitmyer, Jr., Registration No. 33,558
Steven B. Simonis, Registration No. 54,449
Attorneys for Applicants
ST.ONGE STEWARD JOHNSTON & REENS LLC
986 Bedford Street
Stamford, CT 06905-5619
203 324-6155